

## REMARKS

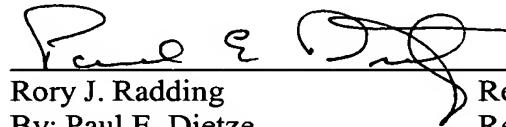
Claims 32, 36-37, 44, 53, and 55 were amended to correct a typographical error wherein the units --  $\mu\text{m}$  -- were inadvertently entered as "mm" (See, e.g., Specification, page 6, lines 23, 27, and 28 and page 7, line 17, 18, and 21). Claims 44 and 50 were simply amended to correct their dependency.

In light of the above amendments and remarks, the Applicant respectfully requests that the Examiner reconsider this application with a view towards allowance. The Examiner is invited to call the undersigned attorney if a telephone call could help resolve any remaining items.

No fee is believed to be due for this submission. Should any fees be required, please charge such fees to Pennie & Edmonds deposit account no. 16-1150

Respectfully submitted,

Date: May 30, 2003

  
Rory J. Radding  
By: Paul E. Dietze

Reg. No. 28,749  
Reg. No. 45,627

**PENNIE & EDMONDS LLP**  
1667 K Street, N.W.  
Washington, DC 20006  
(202) 496-4400

**Appendix A**  
**Changes to the Claims**  
Application No.: 10/000,297 Filed: December 4, 2001

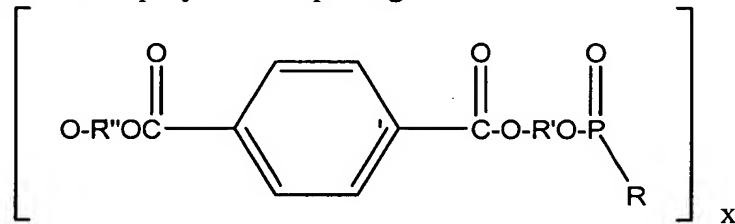
32. (currently amended) The nerve guide conduit of Claims 22, wherein the wall has a thickness of between 150 and 250 μm mm.

36. (currently amended) The nerve guide conduit of Claim 34, wherein each layer is between 20 and 30 μm mm thick

37. (currently amended) The nerve guide conduit of Claim 36, wherein each layer is 25 μm mm thick.

44. (currently amended) The nerve guide conduit of Claim 40 43, wherein the cationic polymer or lipid comprises Transfast or GenePORTER.

50. (currently amended) The nerve guide conduit of Claim 48 49, wherein the microspheres are made from a polymer comprising the subunit



wherein R' is ethyl or butyl and R and R'' are each a suitable side chain or a cross linking agent.

52. (currently amended) The nerve guide conduit of any one of Claims 48 to 51 50, wherein the average diameter of the microspheres is between 5 and 20 μm.

53. (currently amended) The nerve guide conduit of Claim 52, wherein the average diameter of the microspheres is 10 μm mm.

55. (currently amended) The nerve guide conduit of Claim 48, wherein at least 100mm of protein is loaded per 10 μm mm of conduit.

**Appendix B**  
**Currently Pending Claims**  
**Application No.: 10/000,297 Filed: December 4, 2001**

22. A nerve guide conduit comprising a poly(phosphoester) polymer in the shape of a tube having a diameter, a first end, a second end, and a wall having an outer surface and a luminal surface.
23. A nerve guide conduit comprising a polymer according to Claim 1.
24. The nerve guide conduit of Claim 22, wherein the polymer has an average molecular weight of between 10,000 and 25,000.
25. The nerve guide conduit of Claim 24, wherein the polymer has an average molecular weight of between 14,900 and 18,900.
26. The nerve guide conduit of Claim 25, wherein the polymer has an average molecular weight of between 15,000 and 17,000.
27. The nerve guide conduit of Claim 22, wherein the conduit has a surface porosity of between 2 and 58%.
28. The nerve guide conduit of Claim 27, wherein the conduit has a surface porosity of 35%.
29. The nerve guide conduit of Claim 27, wherein the conduit has a surface porosity of 8%.
30. The nerve guide conduit of Claim 22, wherein the tube has a diameter of between 1 and 2 mm.
31. The nerve guide conduit of Claim 30, wherein the diameter is 1.5 mm.
32. (currently amended) The nerve guide conduit of Claims 22, wherein the wall has a thickness of between 150 and 250  $\mu\text{m}$ .

33. (previously amended) The nerve guide conduit of Claim 32, wherein the thickness is between 170 and 240  $\mu\text{m}$ .

34. The nerve guide conduit of Claim 22, wherein the wall comprises a plurality of layers.

35. The nerve guide conduit of Claim 34 comprising at least 3 layers.

36. (currently amended) The nerve guide conduit of Claim 34, wherein each layer is between 20 and 30  $\mu\text{m}$  thick

37. (currently amended) The nerve guide conduit of Claim 36, wherein each layer is 25  $\mu\text{m}$  thick.

38. The nerve guide conduit of Claim 22, wherein the outer surface of the wall has greater microporosity than the luminal surface of the conduit.

39. The nerve guide conduit of Claim 22 further comprising a gene delivery system.

40. The nerve guide conduit of Claim 39, wherein the gene delivery system comprises a complex of DNA and a cationic polymer or lipid loaded into the conduit.

41. The nerve guide conduit of Claim 40, wherein the complex is particles of 20nm in diameter.

42. The nerve guide conduit of Claim 40, wherein the cationic polymer or lipid comprises polyethylenimine, poly-L-lysine, or chitosan.

43. The nerve guide conduit of Claim 40, wherein the cationic polymer or lipid comprises 1,2 - dioleoyl phosphatidylethanolamine.

44. (currently amended) The nerve guide conduit of Claim 40, wherein the cationic polymer or lipid comprises Transfast or GenePORTER.

45. The nerve guide conduit of any one of Claims 39 to 44, wherein the gene encodes a neurotrophic protein or a neuro-active neural fibre growth eliciting molecule.

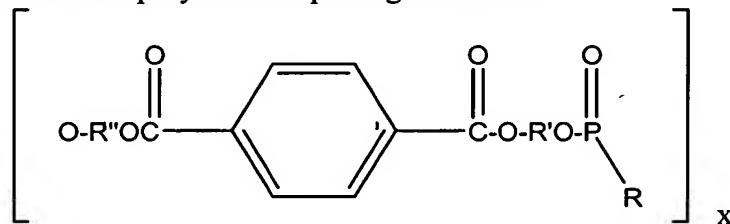
46. The nerve guide conduit of Claim 45, wherein the gene comprises NGF, BDNF or Bcl-2.

47. The nerve guide conduit of Claim 22, further comprising a sustained protein delivery system.

48. The nerve guide conduit of Claim 47, wherein the sustained protein delivery system comprises one or more microspheres loaded into the conduit, wherein the microspheres contain a protein that is released from the microspheres progressively.

49. The nerve guide conduit of Claim 48, wherein the microspheres are made from a poly(phosphoester) polymer.

50. (currently amended) The nerve guide conduit of Claim 48, wherein the microspheres are made from a polymer comprising the subunit



wherein R' is ethyl or butyl and R and R" are each a suitable side chain or a cross linking agent.

51. The nerve guide conduit of Claim 48, wherein the microspheres are made from poly(lactic-co-glycolic acid) or poly(lactide-co-glycolide).

52. (currently amended) The nerve guide conduit of any one of Claims 48 to 51, wherein the average diameter of the microspheres is between 5 and 20  $\mu\text{m}$ .

53. (currently amended) The nerve guide conduit of Claim 52, wherein the average diameter of the microspheres is 10  $\mu\text{m}$ .

54. The nerve guide conduit of Claim 48, wherein the microspheres release the protein over a period of at least three months.

55. (currently amended) The nerve guide conduit of Claim 48, wherein at least 100mm of protein is loaded per 10  $\mu\text{m}$  of conduit.

56. The nerve guide conduit of Claim 47, wherein the sustained protein delivery system comprises NGF, BDNF, CNTF, epidermal growth factor or fibroblast growth factor.

57. The nerve guide conduit of Claim 22, wherein the conduit is loaded with a bioartificial nerve graft comprising Schwann cells.